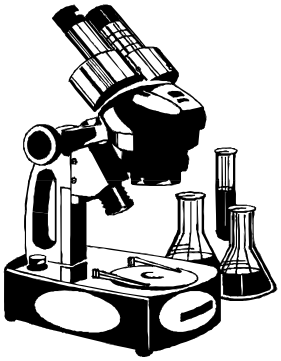


CLIA BITS

North Dakota Department of Health
Division of Health Facilities

Summer 2002

Personnel Quality Assurance Review

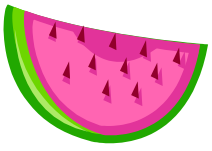
Quality personnel are the key to good laboratory services. Personnel with the proper experience and training are necessary to perform testing accurately. Poorly trained staff can lead to staff turnover and an increase in the number of laboratory errors.

Once a new employee is hired, review the orientation process and checklist with the new employee. Make sure all areas of the laboratory and practice are included in the introduction to the new work environment. The new employee should read all laboratory testing and office procedures. Be sure to document all training. Both the new employee and the trainer should sign and date the training record. Set up a personnel file for each employee.

During the first year of employment, conduct a personnel performance evaluation at six months and 12 months. Thereafter, the employee review is performed annually. The annual review must include direct observations of routine patient test performance, including patient preparation, specimen handling, processing and testing; monitoring the recording and reporting of test results, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; and assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples and assessment of problem-solving skills. It is also good practice to document continuing education as part of the annual review.

Personnel review is one quality assurance topic that can be performed annually. Document the findings on a quality assurance review form. Look to see if all documentation is in the personnel file, if all evaluations are performed annually and if the training set up in your laboratory is producing qualified, highly competent employees.

(Article modified from COLA Insights, April/May 2002)



Antimicrobial Resistance Testing

Although technically referred to as antimicrobial susceptibility testing (AST), detection of antimicrobial resistance has garnered a lot of attention in the past few years. Despite the availability of commercial systems for dilution AST, the disk diffusion

method remains the least expensive and easiest to perform test for the detection of antimicrobial susceptibility and resistance. Like any laboratory test, misleading results are possible if attention to detail is not followed during each phase of the AST test cycle. The current NCCLS (formerly the National Committee for Clinical Laboratory Standardization) disk diffusion test is popularly called the Kirby-Bauer method. NCCLS has been involved in the ongoing process of developing and revising standards for media test method and interpretation of AST results for many years. This article will discuss some of the key elements of NCCLS document M2, Performance Standards for Antimicrobial Disk Susceptibility Tests, now in its seventh edition. Every laboratory that is performing disk AST should have a reference copy of this standard, as well as the most current edition of the annual supplement: document M100, Performance Standards for Antimicrobial Susceptibility Testing.

M2 describes specific requirements for material, methods and practices that are essential to obtain high quality disk diffusion susceptibility results. M100 contains detailed information on interpretation of zone diameters and the quality control guidelines that are the most widely used international standard for disk susceptibility testing. M2 is both a technical reference and a procedure manual. Following a description of the method and of indications for performing disk AST, Section 3 introduces the need for each laboratory to select the combination of antimicrobial agents that will be tested routinely against each specific bacterial group, the so called drug-bug combinations. This section of M2 describes the general concepts that are detailed in Tables 1 and 1A of M100 and which drug-bug combinations should be included for routine reporting to physicians.

Of particular importance is a brief explanation of the various FDA-approved drug classes in use today. It is important to be familiar with the generic names of the drugs you are testing and reporting as well as the class or subclass names into which they are grouped.

The reagents needed and procedures for performing the disk diffusion test are described in M2, Sections 4 and 5. It may be useful to review paragraph 5.4 on reading plates and interpreting results to be sure that you carry out this crucial step appropriately.

Section 6 of M2 describes the method to use for testing fastidious or problem organisms. These organisms require special media, atmosphere or extended incubation times that differ from those for non-fastidious organisms.

The quality control procedures needed to ensure accurate disk AST results are detailed in Section 9 of M2. Take special note of the listing of recommended quality control strains and instructions on strain maintenance and long-term storage.

M100 contains supplement tables. Table 1 lists suggested groupings that should be considered for routine testing and Table 1A lists suggested groupings for fastidious organisms.

More information about antimicrobial resistance is available at:
www.phppo.cdc.gov/dls/master/default.asp

(Article modified from COLA Insights, April/May 2002)